UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff,

v.

MERCK & CO, INC., et al.,

Defendants.

Case No. 13-cv-04057-BLF

ORDER DENYING GILEAD'S MOTION FOR SUMMARY JUDGMENT AND GRANTING MERCK'S MOTION FOR SUMMARY JUDGMENT

[Re: ECF 164-4, 167]

Plaintiff Gilead Sciences, Inc. ("Gilead") brings this declaratory relief action, asking the Court to declare that the manufacture, sale, and use of its drug sofosbuvir does not infringe two patents owned by Defendants, Merck & Co., Merck Sharp and Dohme Corp., and Isis Pharmaceuticals, Inc. (collectively "Merck"), U.S. Patent Nos. 7,105,499 ("the '499 Patent") and 8,481,712 ("the '712 Patent") (collectively, "the asserted patents"). Before the Court are Gilead's motion for summary judgment of invalidity, ECF 164-4, and Merck's motion for summary judgment of direct, induced, and contributory infringement, ECF 167. The Court, having considered the briefing submitted by the parties and the oral argument presented at the hearing on December 10, 2015, DENIES Gilead's motion for summary judgment and GRANTS Merck's motion for summary judgment for the reasons stated below.

I. BACKGROUND

A. Factual Background

Hepatitis C, first identified in 1989, is an infectious disease caused by the hepatitis C virus

(HCV). Exh. 75 to Gilead Mot. ¶ 33, ECF 164-34. Untreated, HCV leads to liver disease and is the primary cause of liver cancer and liver transplants. Exh. 1 to Gilead Mot. at 1:29-33, 1:40-42, ECF 165-1. Until recently, doctors treated HCV with interferon or a combination of interferon plus ribavirin. Exh. 75 to Gilead Mot. ¶ 36, ECF 164-34. These treatments were approximately 50% effective and had significant side effects. Exh. 41 to Gilead Mot. at 8, ECF 164-4. As a result, researchers attempted to find better treatments for HCV. Exh. 1 to Gilead Mot. at 1:45-2:30, ECF ECF 165-1.

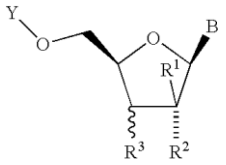
On December 6, 2013, Gilead received approval from the Food and Drug Administration to market and sell Solvaldi®, an orally-administered prescription drug containing the active ingredient sofosbuvir, to treat chronic HCV infection in patients. Order Construing Claims at 2, ECF 140. Sofosbuvir is a prodrug, and is inactive and has little to no therapeutic effect until transformed by enzymes in the body into an active form. *Id*. Once inside a liver cell, sofosbuvir is converted into three analogs, each with different structures: a monophosphate analog, a diphosphate analog, and a triphosphate analog. *Id*. The triphosphate analog is the therapeutically effective form, and can target and cure HCV infection in patients. *Id*.

Merck asserts that two of its patents, U.S. Patent No. 7,105,499 and U.S. Patent No. 8,481,712, cover sofosbuvir, and that Gilead's sales of Sovaldi® and Harvoni®, products which contain the active ingredient sofosbuvir, induce and contribute to the infringement of these patents. Merck Mot., ECF 167. The operative filing date of the '499 and '712 Patents is January 18, 2002. Exh. 22 to Gilead Mot. at Interrog. No. 1, ECF 164-16.

The '712 Patent is directed to compounds having a specific structural formula, Exh. 16 to Gilead Mot. at 143:1-146:60, ECF 165-11, while the '499 Patent relates to methods for treating hepatitis C by administering a therapeutically effective amount of those compounds either alone or in combination with another hepatitis C treatment. Exh. 1 to Gilead Mot. at 137:1-138:25 (claims 1 and 2). The '499 Patent contains two claims and independent claim 1 of the '499 Patent provides:

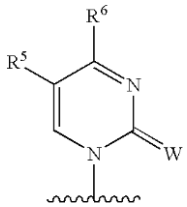
> 1. A method of treating hepatitis C virus (HCV) infection comprising administering to a mammal in need of such treatment a therapeutically effective amount of a compound of structural formula III, or a

pharmaceutically acceptable salt or acyl derivatives thereof,



(III)

wherein B is



W is O or S;

Y is H, C_1-10 alkylcarbonyl, $P_3O_9H_4$, $P_2O_6H_3$, or $P(O)R^9R^{10}$;

R^1 is CF_3, or C_{1-4} alkyl and one of R^2 and R^3 is OH or C_{1-4} alkoxy and the other of R^2 and R^3 is fluoro;

R^6 is H, OH, SH, NH_2, C_{1-4} alkylamino, di(C_{1-4} alkyl)amino, C_{3-6} cycloalkylamino, halogen, C_{1-4} alkyl, C_{1-4} alkoxy, or CF_3;

R^5 is H, C_{1-6} alkyl, C_{2-6} alkenyl, C_{2-6} alkynyl, C_{1-4} alkylamino, CF_3, or halogen; and

R^9 and R^{10} are each independently hydroxy, $OCH_2CH_2SC(=O)$t-butyl, or $OCH_2O(C=O)$iPr.

The '499 and '712 specifications, while not identical, contain the same substantive disclosures and are treated as identical for purposes of these motions. *See, e.g.* Exh, 76 to Gilead Mot. ¶ 55 n. 14, ECF 164-36; Exh. 51 to Merck Opp. ¶ 59, ECF 178-83.

B. Procedural Background

Gilead filed this declaratory judgment action on August 30, 2013. ECF 1. On November 28, 2014, Merck filed its second amended counterclaims. ECF 98. On December 15, 2014, Gilead filed an answer to the second amended counterclaims. ECF101. The Court held a *Markman* hearing on April 3, 2015, ECF 120, and issued its order construing claims on May 1, 2015, ECF 140. On October 29, 2015, the parties filed for summary judgment, ECF 164-4 and

167, and a hearing was held on December 10, 2015, ECF 199.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 56 governs motions for summary judgment. Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "Partial summary judgment that falls short of a final determination, even of a single claim, is authorized by Rule 56 in order to limit the issues to be tried." *State Farm Fire & Cas. Co. v. Geary*, 699 F. Supp. 756, 759 (N.D. Cal. 1987).

The moving party "bears the burden of showing there is no material factual dispute," *Hill v. R+L Carriers, Inc.*, 690 F. Supp. 2d 1001, 1004 (N.D. Cal. 2010), by "identifying for the court the portions of the materials on file that it believes demonstrate the absence of any genuine issue of material fact." *T.W. Elec. Serv. Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987). In judging evidence at the summary judgment stage, "the Court does not make credibility determinations or weigh conflicting evidence, and is required to draw all inferences in a light most favorable to the nonmoving party." *First Pac. Networks, Inc. v. Atl. Mut. Ins. Co.*, 891 F. Supp. 510, 513–14 (N.D. Cal. 1995). For a court to find that a genuine dispute of material fact exists, "there must be enough doubt for a reasonable trier of fact to find for the [non-moving party]." *Corales v. Bennett*, 567 F.3d 554, 562 (9th Cir. 2009).

III. DISCUSSION

A. Gilead's Motion for Summary Judgment of Invalidity

Gilead moves for summary judgment on the grounds that the '499 and '712 Patents are invalid under 35 U.S.C. § 112 for failing to meet the utility prong of enablement. Mot., ECF 164-4. "The enablement requirement of 35 U.S.C. § 112, ¶ 1 requires that the specification adequately discloses to one skilled in the relevant art how to make, or in the case of a process, how to carry out, the claimed invention without undue experimentation. The utility requirement of 35 U.S.C. § 101 mandates that any patentable invention be useful and, accordingly, the subject matter of the claim must be operable. If a patent claim fails to meet the utility requirement because it is not

useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *In re '318 Patent Litig.*, 583 F.3d 1317, 1323-24 (Fed. Cir. 2009) (emphasis omitted) (quoting *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999)). As a result, "the how to use prong of section 112 [requires] that the specification disclose as a matter of fact a practical utility for the invention." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005) (quoting *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999)).

The law imposes a practical utility requirement to prevent the patenting of mere ideas, research proposals, and hypotheses. *In re '318 Patent Litig.*, 583 F.3d at 1324. That is because "[a]llowing ideas, research proposals or objects only of research to be patented has the potential to give priority to the wrong party…" *Id.* "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." *Brenner v. Mason*, 383 U.S. 519, 536 (1966).

"In the context of determining whether sufficient utility as a drug, medicant, and the like in human therapy has been alleged, it is proper…to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct." *CreAgri, Inc. v. Pinnaclife, Inc.*, Case No. 11-CV-6635-LHK 2013 WL 6673676, at *16 (N.D. Cal. Dec. 18, 2013) (quoting *Rasmusson*, 413 F.3d at 1323). Testing or human trials are not required in order for there to be substantiating evidence. *In re '318 Patent Litig.*, 583 F.3d at 1324.

Enablement is determined as of the filing date of the patent application. *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995). The burden is on one challenging validity to show, by clear and convincing evidence, that the specification is not enabling. *See Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) (citation omitted).

Gilead argues that in 2002, one having ordinary skill in the art ("skilled artisan") would not have accepted the assertion that the nucleoside compounds claimed by the asserted patents could treat HCV. Mot. 19, ECF 164-4; *see also* Exh. 75 ("Seeger Report") to Mot. ¶¶ 111 ("In my opinion, a person of ordinary skill in this art as of January 2002 would not accept statements in the patent specification that the compounds claimed in the '712 patent or the compounds recited in the

'499 patent's method claims were useful to treat HCV without data."), 118-121, ECF 164-34; Exh. 76 ("Secrist Report") to Mot. ¶¶ 90 ("Skilled artisans would not have accepted, without any supporting data or explanation, that any prodrug could be used with these compounds in a method of treating HCV."), 212-220, ECF 164-36. According to Gilead's experts, in January 2002, treating HCV with nucleosides was a newly developing field and there was no reliable data of any compounds having relevant anti-HCV activity. *See, e.g.* Exh. 75 ("Seeger Report") to Mot. ¶ 96 ("I am not aware of any published literature describing the activity of nucleoside inhibitors in the HCV replicon assay."), ECF 164-34; Exh. 76 ("Secrist Report") to Mot. ¶ 217 (Skilled artisans would have required data for "a method of treating HCV particularly because the field was just emerging in the 2000-2002 timeframe."), ECF 164-36; Exh. 77 ("Stella Report") to Mot. ¶ 107 ("I have explained that the art of drug delivery using prodrugs is complex and unpredictable. The prior art recognized that there were many options but that there was no single option that would work for all nucleotide compounds."), ECF 164-38. Finally, Gilead argues that whether any nucleoside compound or prodrug had anti-HCV activity was highly unpredictable because subtle changes in known chemical compounds could have significantly different effects on a human body. *See* Exh. 75 ("Seeger Report") to Mot. ¶ 120 ("[T]he activity of nucleoside derivatives against HCV was, and is, an unpredictable field in which small changes to a molecule can cause large changes in biological activity or toxicity…"), ECF 164-34; Exh. 76 ("Secrist Report") to Mot. ¶ 236 ("…the unpredictability of the field…"). ECF 164-36; Exh. 77 ("Stella Report") to Mot. ¶ 71 ("Determining what prodrug might work for a given compound to successfully deliver that compound to the target cells to treat HCV is unpredictable…"), ECF 164-38. As a result, Gilead claims that the lack of reliable data on compounds that have anti-HCV activity, coupled with the high level of unpredictability in the field, would have led a skilled artisan to question the methods claimed in the '499 Patent or the compounds claimed in the '712 Patent.

Merck responds by arguing that a skilled artisan would have understood the methods and compounds claimed in the asserted patents would be useful in treating HCV. Opp. 18, ECF 177-4. According to Merck's expert, Dr. Wentland, the specifications of the '499 and '712 Patents "would have provided the person of ordinary skill in the art sufficient information to understand

the utility of the claimed methods and compounds." Exh. 56 ("Wentland Report") to Opp. ¶ 71, ECF 177-18. Merck also argues that there was ample data by January 2002 that indicated nucleoside analogs could treat viral infections such as HCV. *See, e.g.*, Exh. 6 to Opp. 9, ECF 178-38 ("Nucleoside analogues have been the cornerstone of antiviral therapy over the past 30 years."). Merck notes that by 2002, the Food and Drug Administration approved at least 17 nucleoside analogs for treating viral infections, including HCV, *see* Opp. 8-9, ECF 177-4 (citing Exh. 7-43, ECF 178-39-75), and that there was data as early as 1999 suggesting nucleosides were useful in treating HCV, Exh. 52 to Opp. at 11:9-13, 79:14-25, ECF 178-84 ("The 2'-fluoronucleosides are biologically active molecules which are useful in the treatment of hepatitis B, hepatitis C or HIV…Compounds can exhibit anti-hepatitis C activity by inhibiting HCV polymerase, by inhibiting other enzymes needed in the replication cycle, or by other known methods.").

The Court agrees with Merck, and finds that there is enough evidence to create a disputed issue of material fact as to whether a skilled artisan would have "accept[ed] the allegations [in the asserted patents] as obviously correct." Gilead has put forth evidence, through the testimony of its experts, that show a skilled artisan would have questioned the alleged utility of the asserted patents. *See* Exh. 75 ("Seeger Report"), Exh. 76 ("Secrist Report"), Exh. 77 ("Stella Report") to Mot. ECF 164-34,36,38. As a result, the burden shifts to Merck to present evidence that indicates there is a disputed issue of material fact.

The evidence presented by Merck demonstrates that a skilled artisan could have accepted without the question the alleged utility of the asserted patents. According to Merck's expert, the specifications of the asserted patents contained enough information for one of ordinary skill to understand the utility of the claimed methods and compounds, and there was ample data at the time suggesting nucleoside analogs could treat HCV. *See* Exh. 56 ("Wentland Report") to Opp., ECF 177-18. Drawing all reasonable inferences in favor of Merck, the non-moving party, a reasonable jury could credit Merck's evidence and find a skilled artisan would have accepted the alleged utility of the asserted patents. Thus, at this juncture, the Court cannot rule as a matter of law, based on the undisputed facts, that one of ordinary skill in the art would not have accepted the alleged utility of the asserted patents without question. *See, e.g.*, *Butamax Advanced Biofuels LLC*

v. Gevo, Inc., Case No. 12-1036-SLR, 2015 WL 4611285, at *8 (D. Del. Aug. 3, 2015) ("The disagreement between the experts…and whether the inventors had possession of the invention present genuine disputes of material fact better left to the province of the jury."). Accordingly, the Court DENIES Gilead's motion for summary judgment.[1]

B. Merck's Motion for Summary Judgment of Infringement

Merck moves for summary judgment that (1) the patients and caregivers who use Solvaldi® sold by Gilead directly infringe claims 1 and 2 of the '499 Patent; (2) the patients and caregivers who use Harvoni® sold by Gilead directly infringe claims 1 and 2 of the '499 Patent; (3) patients who use Solvaldi® or Harvoni® directly infringe claims 1-3, 5, 7, and 9-11 of the '712 Patent; (4) Gilead's sale of Solvaldi® or Harvoni® induces the preceding acts of direct infringement of the '499 and '712 Patents; and (5) Gilead's sale of Solvaldi® or Harvoni® contributes to the preceding acts of direct infringement of the '499 and '712 Patents. Mot. 1, ECF 167.

Gilead does not contest Merck's claims of infringement but argues its defense to infringement is that Merck's patents are invalid. Opp. 1, ECF 175. However, Gilead also requests that if its motion for summary judgment of invalidity is denied, then a ruling on Merck's motion be withheld until the jury considers the invalidity of the asserted patents. *Id*. at 2. According to Gilead, it may significantly prejudice a jury if they learn of an infringement finding before invalidity is decided. *Id*.

Since Gilead does not contest Merck's motion for summary judgment, the Court GRANTS Merck's motion. As to whether the jury should be informed of the Court's ruling on Merck's motion, and if so, how it should be presented, the Court finds these issues are better left for the final pretrial conference. For clarity, the Court emphasizes that this ruling is only to infringement but not ultimate liability because of Gilead's outstanding invalidity defenses.

[1] Since Gilead has not come forward with undisputed facts showing that a skilled artisan would not have accepted the claimed utility of the asserted patents without question, the Court does not need to reach the second step of the practical utility analysis of whether substantiating evidence exists to support the asserted patents' claimed utility.

IV. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that:

1. Gilead's motion for summary judgment is DENIED.

2. Merck's motion for summary judgment is GRANTED.

IT IS SO ORDERED.

Dated: February 1, 2016

BETH LABSON FREEMAN
United States District Judge